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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,016	12/04/2001	Kenneth Martin Levin	6535/53651	8264

30505 7590 03/29/2004

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EXAMINER

LEWIS, KIM M

ART UNIT	PAPER NUMBER
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3761

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DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/005,016

Applicant(s)

LEVIN, KENNETH MARTIN

Examiner

Kim M. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2003.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☒ Claim(s) 16-21 is/are allowed.  
6) ☒ Claim(s) 1,3-15 and 22 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☒ Other: Detailed Action.

## DETAILED ACTION

### ***Response to Amendment***

The amendment filed on 12/30/03 has been received and made of record in the application file wrapper. As requested, claims 1, 3-6, 8, 9 and 11-14 have been amended, claim 2 has been canceled and claim 22 has been added.

Claims 1 and 3-22 are pending in the instant application.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 3-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,181,905 ("Flam").

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As regards claim 1, Flam discloses an adhesive bandage for monitoring the condition of a wound. As can be seen from fig. 5, the bandage (31) comprises a backing film (34), an adhesive layer (32) and a dressing in the form of a layer of polymeric foam (33). Flam also discloses tape (11), which is adhered to the top surface of backing (34).

As to the backing being flexible, it is inherent in the disclosure that the backing is flexible given the environment in which the bandage is use. Assuming arguendo that the applicant contends that the backing is not flexible, the examiner contends that one having ordinary skill in the art would have found it obvious to provide the bandage of Flam with a flexible backing in order to contour the skin of the user.

Flam additionally discloses that the tape as shown in Fig. 1, comprises markings in the form of text, which indicate care instructions for a wound (col. 4, lines 56-62). Flam fails to teach text markings specifying care instructions for a wound. However, the examiner contends that since the markings of Flam indicate wound care instructions, one having ordinary skill in the art would have been motivated to substitute the text markings for specific instructions as an obvious alternative to communicate the type of wound care that should be provided to a patient.

As regards claims 3-13 and 22 Flam fails to teach the markings indicate the day the bandage was applied, the day the bandage should be changed, proscriptive care instructions, where additional text or indicia should be added to the bandage, that the markings include lines or the addition of text or other wound care instructions, that the care instructions reference a wound protocol, that the color is associated with a

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particular day of the week and wherein the adhesive bandage was applied on that day of the week and that the color is associated with a particular day of the week (temporal parameter) and wherein the adhesive bandage should be changed on that day of the week.

Flam has already established that certain color markings represent a certain temperature range, which translates to administering a certain treatment. The examiner contends that it then follows that one having ordinary skill in the art would find it an obvious design choice to modify the tape of Flam to include indicia of any kind including text, markings, lines, colors, etc., which represents, indicates or specifies various activities, days, protocols, temporal parameters as recited in claim 11 (also note the rejection of claim 1 above), wound care instructions including when the bandage should be changed and how often, etc.

As regards claim 14, tape (11) can be the adhesive label that includes the text markings indicating wound care instructions.

As regards claim 15, it can be seen from Fig. 5 that the adhesive covers the adhesive covers substantially the entire adhesive-faced side of the backing film.

***Allowable Subject Matter***

Claims 16-21 are allowed.

### ***Response to Arguments***

In response to applicant's arguments, which apply to the newly amended claims, please note the new rejections above.

In response to applicants regarding claim 7, that allowing healthcare workers to overwrite the boxes with text would obscure the indicators and defeat the actual purpose of Flam's invention, the examiner disagrees. The examiner takes the position that after the bandage is placed on the user and a box has changed color, the healthcare provider can place text in the box to indicate which box changed color. Also, a box can be pre-marked so as to indicate a danger level (*i.e.*, when a temperature is reached that is too high, a box can be pre-marked with a danger indicator). Additionally, the entire box does not have to be covered.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 4,947,867 issued to Keeton discloses surgical clothing And labeling means therefor.

U.S. Patent No. 5,498,034 issued to Ford discloses a patient care information system.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is

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703.308.1191. The examiner can normally be reached on Monday to Wednesday from 5:30 am to 4:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kim M. Lewis  
Primary Examiner  
Art Unit 3761

kml  
March 21, 2004